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February 5, 2021

VIA EMAIL
Nakul Y. Shah, Esq.
Hill Wallack LLP
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08540

Re: **In re Valsartan, Losartan, and Irbesartan Liability Litigation**
Case No. 1:19-md-02875-RBK-KMW

Counsel:

I write to address significant deficiencies in the Hetero Drugs Limited and Hetero Labs Limited ("hereinafter referred to as "Hetero") production as well as begin discussions regarding the rescheduling of upcoming depositions. In light of the short extension of discovery deadlines per the February 3, 2021 hearing with Judge Vanaskie and Special Master Order No. 2, we request a prompt response to each issue listed, including whether and by when the issue will be fully addressed and remedied. If we cannot reach agreement, we intend to raise all unresolved issues at the upcoming discovery conference next week. In addition to our request for a written response to these issues, we are available to meet and confer as soon as possible.

First, Hetero has not produced custodial files for the following custodians, some of whom are also deponents. This is a significant issue for obvious reasons.

1) Dr. B.V. Ramireddy (Deponent)
2) Dr. Manoranjan Kumar (Deponent)
3) Dr. Murali Nagabelli (Deponent)
4) Jyothi Ganti (Deponent)
5) Mohan Reddy Chilukuri (Deponent)
6) D. China Venkata Reddy
7) Sridhar Badduri Reddy
8) Ramakrishna B
9) Rajesh Khanna S
10) Suresh Reddy Boddapati

Assuming that Defendants produce the above custodial files immediately pursuant to its discovery obligations, in full compliance with the ESI Protocol, Plaintiffs propose the dates below for the rescheduling of Hetero's deponents:

Venkata Pravin Kumar Penubaka – February 18-19, 2021

Bandaru ("B.V. Rama Rao") Venkata Ramarao – February 22-23, 2021

Dr. Murali Nagabeli – March 9-10, 2021

Panchakshari Nanyappa Gowda – March 23-25, 2021

Venkataramana Madireddy – March 29-31, 2021

Dr. Manoranjan Kumar – April 5-6, 2021

Dr. B.V. Ramireddy – April 13-14, 2021

In addition, Plaintiffs propose that Jyothi Ganti, Yogeshwar Reddy Mamilla, and Mohan Reddy Chilukurri be deposed in May. These dates, especially those in February, are premised of

course on Hetero making full custodial productions for the aforementioned agreed upon custodians and deponents, and complete production of other outstanding documents, immediately.

Second, there are aspects of Hetero's production that are not compliant with the ESI Protocol. This includes Hetero's Production Index, which is not in compliance with Section III, Paragraph I of the Electronic Discovery Protocol. Pursuant to Section III, Paragraph I, "Each production also contain a Production Index, which shall be updated with each production, setting forth (1) dates, (2) Bates number range, (3) source(s) *(e.g.,* custodians, database) of the materials contained in each production volume, (4) whether the production was a replacement production, and (5) the date of withdrawal of protected designation and replacement with no protected designation for applicable Bates ranges, if applicable. Hetero's most recent Production Index dated November 30, 2020 simply states "Completed custodial document productions for all custodians" for Bates numbers HLL00478112-HLL1234918. This description is not compliant with the terms of the Electronic Discovery Protocol and Plaintiffs request a compliant Production Index that properly describes the sources/custodians of the documents be produced within 7 days. Another issue with the productions is the insufficient metadata, including documents listing "Created and "Modified" dates of "12/31/9999", non-compliant formats for Custodian fields which should list Custodians as "LASTNAME, FIRSTNAME, MIDDLENAME", Custodian fields that simply list "Hetero," and missing Author and Duplicate Custodian fields.

Third, there are deficiencies in the Privilege Log produced by Hetero. Section V, Paragraph A of the Electronic Discovery Protocol requires the producing party to provide an updated summary log with each production, identifying any information withheld or redacted based on the assertion of privilege, in an electronically searchable format (e.g., Excel), containing, for each document claimed as privileged, a description of "the nature of the documents,

communications, or tangible things not produced or disclosed - and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim," pursuant to Fed. R. Civ. P. 26(b)(5)(A). The descriptions and information provided in Hetero's Privilege Logs do not provide Plaintiffs sufficient information to challenge these privilege designations, and are thus in violation of the Federal Rules, and the applicable case law in this district. This includes the inadequate descriptions of the substance of the documents in question. For example, there are over 40 separate entries that state the same "Description" as the basis for the privilege designation: "Attachment provided at the request of counsel in connection with pending litigation requesting and providing information to facilitate the rendition of legal advice regarding discovery requests in Cain-Ament matter." There are also over 35 entries that simply list "Draft submission containing counsel's legal advice regarding FDA inspection report" as the basis for the privilege designation. These entries, among others, lack adequate identification of those who sent or received emails or other communications, including the lack of identification of the attorney(s) involved or a detailed explanation of why their involvement renders the communication privileged. Accordingly, Plaintiffs request Hetero produce a compliant Privilege Log with an accompanying "cast of characters" listing the name, title, department, and email address of each person named in the Privilege Log so Plaintiffs can reasonably evaluate the privilege claims.

Fourth, in the process of preparing for the first depositions, which are now being rescheduled, we identified documents that do not appear to have been produced, or in the alternative if produced simply could not be located by our reviewers based on the manner of the production. These documents include the following (since the review continues, this list cannot be confirmed as fully comprehensive and we reserve the right to continue to request production or

identification of documents – and we expect that you will also take all necessary steps to independently identify deficiencies in the production as you are obligated to do):

1. Complete production of all versions of all internal SOP's, Quality Manuals, Core Procedures, and other related documents addressing quality and cGMP obligations in accordance with the Rule 34 document requests and the 30(b)(6) topics – and this includes all iterations from the first to the present, and all drafts. For example, a partial set of draft Core Procedures was produced per an email circulated on July 11, 2017 (HLL366561-366673), but we see no prior versions or final or subsequent versions. Several of the following listed items specifically identify documents falling into this category that do not appear to have been produced.

2. The only Quality Manual that appears to have been produced is dated August 20, 2018, Bates numbers HLL094339 – HLL094378. Based on our review this was not the first and only Quality Manual in use at Hetero, as there are explicit references to prior version(s), yet the prior versions and any subsequent versions were not produced.

3. All Site Master Files for the locations where the API and Finished Dose sold in the US were manufactured do not appear to have been produced.

4. Standard Operating Procedures for which we have been unable to locate all versions include (we reiterate it is your obligation to ensure complete production, confirmed as such by your client and the designated 30(b)(6) witnesses):

   a) Standard Operating Procedure QC006-05 Testing and Release of Inprocess/Finished product samples and all versions and any revisions of the same that were effective throughout the relevant time period;

b) Standard Operating Procedure QC004-15 Sampling, Testing, and Release of Raw Materials and all versions and any revisions of the same that were effective throughout the relevant time period;

c) Standard Operating Procedure QC008-09 Good Laboratory Practices and all versions and any revisions of the same that were effective throughout the relevant time period;

d) Standard Operating Procedure QC014-07 Qualification of analyst in quality control and all versions and any revisions of the same that were effective throughout the relevant time period;

e) Standard Operating Procedure QC015-02 Reporting of analytical results and all versions and any revisions of the same that were effective throughout the relevant time period;

f) Standard Operating Procedure QC047-05 Analytical method verification effective January 12, 2018 and all versions and any revisions of the same that were effective throughout the relevant time period;

g) Core Operating Procedure 01-026-04 Trend Analysis and Handling Out of Trend Results and all versions and any revisions of the same that were effective throughout the relevant time period

h) Standard Operating Procedure QC018-10 Retesting of Materials and all versions and any revisions of the same that were effective throughout relevant time period;

i) Standard Operating Procedure QC025-02 Usage of Liquid Sampler for Sampling of Liquid Raw Material and all versions and any revisions of the same that were effective throughout the relevant time period;

j) Standard Operating Procedure QC176-07 Good Chromatographic Practices and all versions and any revisions of the same that were effective throughout the relevant time period;

k) All versions of the Master SOP Indexes for all relevant departments, including but not limited to, Quality Control, Quality Assurance, Engineering, Microbiology, and Production General Area, do not appear to have been produced.

5. Other documents that we have been unable to locate in the production include the following:

a) Annexure - HLL415848

b) Annexure – HLL415781

c) API Audit Report for Valsartan – all versions (Bates No. for audit reports for other ARBs that were found in the production: HLL00494057; HLL00493999)

d) Please verify that all API and FDF NDMA/NDEA testing results have been disclosed. It appears many of the documents with testing results have batches listed with blank results, as if they are unfinished documents. See examples: HLL00690141 and HLL063697.

Fifth, despite your agreement to produce an Affidavit supporting the identification of topics for Hetero's wholly owned subsidiary Camber to address, that Affidavit has not been provided. This has prevented us from reaching agreement on the scope of testimony to be provided by Camber, and finalizing the 30 b 6 notice for Camber, and scheduling those depositions. Please provide the Affidavit immediately.

Finally, please advise of a date next week when we can meet and confer regarding the quality documents (addressed above) so that we can begin the process of identifying those that

were applicable and are relevant to the 30(b)(6) topics. We expect that the 30(b)(6) designees will work with you to do so, as part of their process of preparation to testify on behalf of your client, so that there are no deficiencies at the time of the depositions. We will also be identifying documents shortly regarding the product tracing/sales and pricing topics and will be looking to meet and confer on that as well.

We look forward to your response.

Very truly yours,

ADAM M. SLATER